

In re National Prescription Opiate Litigation: MDL 2804

**PLAINTIFFS' MEMORANDUM OF LAW IN OPPOSITION TO DEFENDANTS' *DAUBERT*
MOTION TO EXCLUDE THE OPINIONS OFFERED BY JONATHAN GRUBER**

Summary Sheet of Concise Issues Raised

Motion Name: Defendants' *Daubert* Motion to Exclude the Opinions Offered by Jonathan Gruber (Dkt. # 1765)

Concise Description of Issues:

Defendants fall far short of their burden to exclude the opinions of Professor Jonathan Gruber. Prof. Gruber, a prominent health economist from MIT with experience analyzing the economics of addictive behaviors, uses well-accepted economic methodologies and approaches to conclude that increased prescription opioid shipments led to increased harms, including illicit opioid-related harms. His opinions are reliable and relevant, and will assist the trier of fact.

Prof. Gruber used a variety of basic economic tools and applied them to analyze several datasets encompassing more than 20 years of information. Prof. Gruber also relied on peer-reviewed epidemiological and economic studies that similarly conclude that increased prescription opioid shipments caused increased illicit opioid-related harms, a common-sense result this Court has recognized. *See* Op. and Order on Motions to Dismiss, Dkt. # 1203 at 35 (“When there is a flood of highly addictive drugs into a community it is foreseeable—to the point of being a foregone conclusion—that there will be a secondary, “black” market created for those drugs.”). Defendants’ challenges rest on mischaracterizations of Prof. Gruber’s Report and incomplete citations to his deposition testimony. Although Defendants argue that his analysis shows only correlation, not causation (a characterization with which Prof. Gruber does not agree), that issue goes to the weight, not the admissibility, of Prof. Gruber’s testimony.

Professor Gruber’s opinions linking shipments to harms are also plainly relevant to Plaintiffs’ claims that, among other things, Defendants caused an unreasonable interference with the public health and safety in the Bellwether Counties, and that Defendants are liable for the increased costs incurred by these Counties. Prof. Gruber’s national model, which notably also analyzes Bellwether specific data, is clearly helpful in assisting the trier of fact with a framework regarding the impact of shipments on harms, including the illicit opioid-related harms that many areas of the country and in particular the Bellwether Counties have experienced in recent years.

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UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

IN RE NATIONAL PRESCRIPTION

OPIATE LITIGATION

This document relates to:

Track One Cases

MDL 2804

Case No. 17-md-2804

Hon. Dan Aaron Polster

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DAUBERT MOTION TO EXCLUDE THE OPINIONS OFFERED BY
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July 31, 2019

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INTRODUCTION

Professor Jonathan Gruber, a prominent health economist from the Massachusetts Institute of Technology with specific expertise in examining addictive behaviors, performs three important economic analyses relevant to this litigation. First, he conducts *several* empirical and statistical analyses—not just utilization of “quartile-graphs” as narrowly characterized by Defendants¹—to show that, unsurprisingly, greater shipments of prescription opioids led to greater harms across the nation. *See* Report of Professor Jonathan Gruber, Dkt. # 2000-6 (“Gruber Rep.”) ¶ 16. Contrary to Defendants’ mischaracterizations, Prof. Gruber employs well-established economic principles and approaches to establish on an *aggregate* basis that geographic areas receiving higher volumes of per capita shipments of prescription opioids experienced significantly higher rates of opioid related misuse and mortality. *Id.* He comes to this conclusion by utilizing a wide variety of data sets, including shipment, mortality, and opioid use disorder (OUD) data at the county level for nearly twenty years from hundreds of counties across the nation. *Id.* ¶¶ 72-84; *see also* Data Appendix to Gruber Rep. (“Data App’x”) at 1-17.² As a cross-check, Prof. Gruber also analyzes the link between shipments of prescription opioids and crime to establish that higher shipments led to higher levels of crime at the national level – thus reinforcing his opinion that excessive shipments led to greater harms. Gruber Rep., Dkt. # 2000-6 ¶¶ 16; 108-12; *see also* Data App’x at 18-21.

Second, Prof. Gruber conducts empirical and statistical analyses to show that the growth in illicit opioid-related harms, including heroin and fentanyl mortality which has been particularly acute since 2010, was a direct result of shipments of prescription opioids. Gruber Rep., Dkt. # 2000-6 ¶¶ 16; 85-87. Prof. Gruber specifically shows that areas receiving greater shipments experienced greater illicit opioid mortality post-2010, and that illicit opioid mortality rapidly accelerated after changes in

¹ Indeed, the term “quartile graphs” is not mentioned once by Prof. Gruber in his report. Defendants have created this term in a misleading attempt to recast his analysis into something it is not.

² The Data Appendix to Prof. Gruber’s Report was submitted manually to the Court on July 25, 2019. *See* Dkt. # 1999-6. Plaintiffs also attach it hereto in electronic form as Exhibit A.

the prescription opioid marketplace. Prof. Gruber supplements this analysis by providing evidence from epidemiological and economic studies that support his conclusion that illicit harms since 2010 were a direct outgrowth of shipments and licit harms. *Id.* ¶¶ 88-99.

Third, Prof. Gruber again uses basic statistical and empirical tools through the most commonly utilized form of economic analysis, a regression, to conclude that economic, demographic, and social conditions *cannot* explain the emergence of harms from illicit opioids since 2010. *Id.* ¶¶ 100-107. In addition, these regression analyses reflect that only a tiny fraction of the extraordinarily wide differences in opioid shipments per capita across geographic areas can be explained by differences in medical need. *Id.*

Despite the plain relevance and methodologically sound nature of these opinions, Defendants argue that all of Prof. Gruber's opinions are unreliable and do not fit this case, employing a series of misleading attacks that focus on certain graphs from the report and a purported failure to consider the Bellwether Counties. But these complaints are based on misleadingly incomplete representations of Prof. Gruber's report and his deposition testimony. They also ignore the data and academic literature supporting his opinions, and reflect fundamental misunderstandings of his assignment. Defendants' conclusory argument that Prof. Gruber's analysis only shows correlation (which in any event is wrong) also improperly usurps the trier of fact's role to make that determination. For these reasons, none of Defendants' arguments provide a basis under *Daubert's* limited gatekeeping function to exclude Prof. Gruber's opinions, and instead are arguments going to weight that Defendants are free to raise at trial.

LEGAL STANDARDS

Plaintiffs have separately filed a *Daubert* Roadmap Brief setting forth the legal standards generally applicable to expert admissibility challenges, and Plaintiffs adopt and incorporate herein by reference those general standards. *See* Plaintiffs' *Daubert* Roadmap Brief.

ARGUMENT

I. PROFESSOR GRUBER IS HIGHLY QUALIFIED TO OFFER HIS OPINIONS.

Although Defendants do not directly challenge Prof. Gruber's qualifications, his expertise provides useful context for his opinions. Prof. Gruber has unparalleled expertise in the economics of health and public finance, including authoring the leading textbook in this field, *Public Finance and Public Policy*, now in its Sixth edition. Gruber Rep., Dkt. # 2000-6 ¶¶ 2-6; App'x I.A. Directly relevant here, he also has significant experience analyzing the economics of addictive behaviors, including authoring several peer-reviewed papers on the economics of smoking and providing expert testimony in tobacco litigation. *Id.* ¶ 5. Prof. Gruber has also played a key role in developing health care policy at both the federal and state levels for more than two decades, including advising the Obama administration during the development of the Affordable Care Act and Governor Romney and the Massachusetts legislature in developing health care reform in that state. *Id.* ¶ 4. Based on this body of work, Prof. Gruber has won numerous awards and been recognized as one of the most innovative and practical thinkers of our time. *Id.* ¶ 3. Indeed, Defendants' own economic expert has indicated that Prof. Gruber is a "very smart academic researcher[]" and that he has "read many of the papers that [Prof. Gruber has] written, and learned from them."³

Given this background and expertise, it is no surprise that Prof. Gruber has been qualified to testify as an expert in the past. *See, e.g., Int'l Tobacco Partners, Ltd. v. Kline*, 475 F. Supp. 2d 1078, 1082 n. 7 (D. Kan. 2007) ("Gruber is clearly qualified to testify as an expert in this case."). His opinions here provide an important economic perspective, grounded in sound methodologies, regarding the impact of prescription opioids to harms that is directly relevant to Plaintiffs' claims. He is highly qualified to offer expert opinions in this case.

³ *See* Daniel P. Kessler Dep. (05/29/19) at 51:24-52:4. The quoted portions are attached hereto as Exhibit B.

II. PROFESSOR GRUBER’S OPINIONS ARE RELIABLE AND THE PRODUCT OF WELL-RECOGNIZED ECONOMIC PRINCIPLES AND METHODOLOGIES.

Defendants’ challenges to Prof. Gruber’s opinions are premised primarily on their contentions that his methodology is non-existent or unreliable. *See* Defs.’ Daubert Mot. to Exclude the Opinions Offered by Jonathan Gruber, Dkt. # 1765-3 (“Defs.’ Brief”) at 3-12. None of these arguments are correct and all should be rejected by the Court.

A. Professor Gruber’s Graphical Models Reflect Well-Accepted Economic Tools That Have Been Widely Used in Peer-Reviewed Published Literature.

Defendants’ principal attack on Prof. Gruber is based on a mischaracterization of his opinion and the basis for it. They claim that Prof. Gruber’s opinion that there is a direct and causal relationship between opioid shipments and opioid harms is based on nothing more than graphical analyses, and that *all* of Prof. Gruber’s opinions should be excluded because *some* of these graphs are purportedly not based on any accepted economic methodology. *Id.* at 4-5.⁴ Defendants are wrong on both counts. As discussed below, the methodology used to generate the graphs is entirely proper and reliable, and in any case, Prof. Gruber’s opinions are grounded in far more than these particular graphs. In fact, Prof. Gruber used a variety of fundamental tools of economic analyses—including regressions and empirical analyses, which Defendants notably do not challenge (*see e.g.*, Gruber Rep., Dkt. # 2000-6 ¶¶ 46-71; 75-77; App’x I.D), in addition to straightforward statistical modeling reflected in certain figures Defendants do appear to challenge—to arrive at his opinions.

In connection with his opinion that increased shipments led to increased harms, including harms caused by heroin and fentanyl abuse, Prof. Gruber specifically analyzed prescription opioid shipment data covering more than twenty years, mortality rates during that same time period, and OUD rates for a smaller time period. *See id.* ¶¶ 72-87. Furthermore, he examined these data and rates in more than 400 “large” counties for which both mortality and prescription opioid shipment data

⁴ Indeed, Defendants acknowledge that Prof. Gruber’s use of “quartile-based graphical analyses” is limited to just seven of the twenty-five figures contained in his report. *Id.* at 4 (citing to Figures 1.16-1.20, 1.24-1.25 of the Gruber Report).

were available. *Id.* ¶¶ 27, 36; *see also* Data App’x at 1-17. In order to control for the wide variation in prescription opioid shipments across these counties, Prof. Gruber reasonably compared high and low shipment areas to examine the statistical trends that resulted in these areas relative to, among other things, mortality and OUD rates. *Id.* ¶ 78. As explained in further detail below, each of these steps uses well-accepted, widely-used, and reliable tools of economic analyses. Moreover, although Defendants focus much of their challenge on Prof. Gruber’s examination of the highest and lowest quartile areas from the 400-large county sample set, that examination provides some, but notably not all, of the bases for his opinions, and is entirely proper in any event.

This type of basic economic analysis of isolating a subset of data—or in this case, specifically examining high and low shipment areas—is well-accepted and widely used in economics and in particular in healthcare economics. Indeed, numerous peer-reviewed, published economic studies and other literature, including literature cited and authored by Prof. Gruber and referenced in his report, employ basic graphical analyses and illustrations to establish statistical relationships between two or more variables. *See* John M. Chambers, William S. Cleveland, Beat Kleiner, and Paul A. Tukey, *Graphical Methods for Data Analysis*, (CRC Press 2018) (“There is no single statistical tool that is as powerful as a well-chosen graph . . . Even for small sets of data, there are many patterns and relationships that are considerably easier to discern in graphical displays than by any other data analytic method.”)⁵ Defendants nonetheless contend that this methodology is unreliable because it has no

⁵ *See also* Abby Alpert, David Powell and Rosalie Liccardo Pacula, *Supply-Side Drug Policy in the Presence of Substitutes: Evidence from the Introduction of Abuse-Deterrent Opioids*, 10 Am. Econ. Journal: Econ. Policy 1-35 (2018) (utilizing “Graphical Event Study Results” to support the conclusion that large increases in heroin deaths immediately after reformulation occurred in states with the highest initial rates of OxyContin misuse) (cited in Gruber Rep., Dkt. # 2000-6 ¶ 97).

The following studies also authored and cited in Prof. Gruber’s report reflect the use of graphical analyses to establish patterns and relationships in data. *See* Michael D. Frakes and Jonathan Gruber, *Defensive Medicine: Evidence from Military Immunity*, Nat’l Bureau of Econ. Research Working Paper 24846 (July 2018); Benjamin D. Sommers and Jonathan Gruber, *Federal Funding Insulated State Budgets From Increased Spending Related To Medicaid Expansion*, Health Affairs 36 5 (May 2017); Jonathan Gruber and Robin McKnight, *Controlling Health Care Costs through Limited Network Insurance Plans: Evidence from Massachusetts State Employees*, 8(2) Am. Econ. Journal: Econ. Policy 219-250 (2016); Leemore Dafny, Jonathan Gruber and Christopher Ody, *More Insurers Lower Premiums: Evidence from Initial Pricing in the Health Insurance Marketplaces*, 1(1) Am. Journal of Health Econ. 53-81 (2015); Jason Abaluck and Jonathan Gruber, *Choice Inconsistencies among the Elderly: Evidence from Plan Choice in the Medicare Part D Program*, 101 Am. Econ. Review 1180-1210 (June 2011).

specific name. Defendants simply misstate the record when they assert that Prof. Gruber was not able to identify any authoritative source supporting his method at any point during his deposition. *See* Defs.’ Brief at 4. In fact, when asked, Prof. Gruber clearly identified the study using the same economic analysis he utilized to establish causal relationships:

Q. Whether in a textbook or some other source, can you point me to any source that would describe for me the type of, you know, high quartile -- highest quartile-lowest quartile analysis that you’re doing here and would state that that’s an appropriate means to show causation?

THE WITNESS: Sure. The Evans study that we -- Evans, Lieber and Powell study does exactly this kind of analysis ...

Q. And the Evans study doesn’t purport to show causation, does it?

A. Yes, it does.

Jonathan Gruber Dep. (04/25/19), Dkt. # 1962-15 at 405:5-17; 406:15-17.⁶ As a result, Prof. Gruber’s use of graphical analyses to support his opinions—which is entirely reasonable, well-supported, and appropriate in this case—provides no basis whatsoever to exclude his testimony.

B. Professor Gruber’s Opinion That Increased Shipments Led to Increased Harms is Well-Supported by Reliable Evidence.

Prof. Gruber’s fundamental opinion that increased shipments of prescription opioids caused dramatic increases in public health harms, including harms caused by both licit and illicit opioids, is also the product of reliable principles and methodology.

First, the numerous data regarding prescription opioid shipments, opioid mortality, and OUD rates over a twenty-plus year time period in 400-plus counties he relies upon are not anecdotal or isolated. Rather, they show a strong relationship between these factors occurring over an extended

⁶ The Evans study, cited frequently in Prof. Gruber’s report, is a well-publicized and peer-reviewed study that concludes that the rapid increase in heroin deaths following the 2010 time-frame was directly caused by the reformulation of OxyContin, with areas that had greater access to pre-reformulation opioids experiencing greater increases in heroin deaths – a conclusion similar to the one Prof. Gruber arrives at in his report. *See* William N. Evans, Ethan M.J. Lieber, Patrick Power, *How the Reformulation of Oxycontin Ignited the Epidemic*, CI(1) Review of Econ. and Statistics 1-15 (Mar. 2019), https://www.mitpressjournals.org/doi/pdf/10.1162/rest_a_00755.

period of time. *See* Gruber Rep., Dkt. # 2000-6 ¶¶ 79-87. These observed relationships over time are indicia of the reliability of Prof. Gruber’s causation opinion. *See, e.g., Milward v. Acuity Specialty Prods. Grp., Inc.*, 639 F.3d 11, 17 (1st Cir. 2011) (factors that may demonstrate causal relationship include “consistency of the association in varied circumstances”); *DeGidio v. Centocor Ortho Biotech, Inc.*, 3 F. Supp. 3d 674, 678 n. 4 (N.D. Ohio 2014) (same); *see also In re Neurontin Mktg. and Sales Practices Litig.*, 712 F.3d 21, 46 (1st Cir. 2013) (expert opinion in another case that had extrapolated from association at a single point in time “does not come close to resembling Dr. [Meredith] Rosenthal’s evidence, which examined contemporaneous data that reflected what was actually happening with regard to spending and prescriptions while Pfizer’s fraud was ongoing.”).

Second, the strength of the observed relationships between increased prescription opioid shipments and increased harms further evidences the reliability of Prof. Gruber’s causation opinion. In the counties that had the highest per capita shipments between 1997 and 2010, the prescription opioid mortality rate increased over 3.75 times more than it did in the counties with the lowest per capita shipments. *See* Gruber Rep., Dkt. # 2000-6 ¶ 84, Fig. 1.18. The strength of this relationship further underscores the reliability of Prof. Gruber’s causation opinion. *See, e.g., Milward*, 639 F.3d at 17 (“strength or frequency of the association” may help demonstrate causal relationship); *DeGidio*, 3 F. Supp. 3d at 678 n. 4 (same); *see also In re Mirena IUS Levonorgestrel-Related Prods. Liab. Litig.*, 341 F. Supp. 3d 213, 242 (S.D.N.Y. 2018) (“A strong association (large in magnitude) is more likely to represent causation than a weak association (small in magnitude).”) (citation and internal quotation marks omitted); *Hamilton v. Breg, Inc.*, No. 2:09-cv-146, 2011 WL 833614, at *6 (S.D. Ohio Jan. 24, 2011) (“startlingly high” strength of association supported experts’ causation opinion). Moreover, as set forth above, this association and conclusion are consistent with recent economic literature analyzing similar issues, including the Evans and Alpert studies.

Third, in formulating his analysis of the variation in per capita shipments across counties, Prof. Gruber utilized a regression analysis and controlled for a wide variety of variables—such as the counties’ demographic and economic characteristics—and still found that these factors did not explain the observed variation in per capita shipments. *See* Gruber Rep., Dkt. # 2000-6 ¶¶ 75-77; App’x I.D. This regression analysis, a commonly-used and well-accepted econometric tool, further underscores the reliability of his causation opinion. *See, e.g., In re Neurontin*, 712 F.3d at 42 (“[R]egression analysis is a well recognized and scientifically valid approach to understanding statistical data, and courts have long permitted parties to use statistical data to establish causal relationships.”); *Conwood Co., L.P. v. U.S. Tobacco Co.*, 290 F.3d 768, 780 and 793 (6th Cir. 2002) (regression analysis by economic expert, used to establish causation of antitrust injury, was “generally accepted”); *City of Tuscaloosa v. Harcros Chems., Inc.*, 158 F.3d 548, 566 (11th Cir. 1998) (“[M]ultiple regression analysis . . . is well-established as reliable.”); *Petruszki’s IGA Supermarkets, Inc. v. Darling-Delaware Co.*, 998 F.2d 1224, 1238 (3d Cir. 1993) (“First, we note that the scientific method used by the economists, multiple regression analysis, is reliable.”); *Ohio ex rel. Montgomery v. Louis Trauth Dairy, Inc.*, 925 F. Supp. 1247, 1252 (S.D. Ohio 1996) (“Econometric and regression analyses are generally considered reliable disciplines.”); *Reference Manual on Scientific Evidence* (Fed. Jud. Ctr. 3d ed. 2011) (“*Reference Manual*”) at 308 (D. Rubinfeld, *Reference Guide on Multiple Regression*) (“*Multiple Regression*”) (“Because multiple regression is a well-accepted scientific methodology, courts have frequently admitted testimony based on multiple regression studies . . .”).

In trying to undermine Prof. Gruber’s opinions, Defendants resort to isolating data points while ignoring the surrounding analysis in order to manufacture the appearance that he “leaps from correlation to causation.” *See* Defs.’ Brief at 1, 6. But with respect to Defendants’ specific criticisms regarding Prof. Gruber’s analysis of OUD rates, Prof. Gruber described the limited value of considering OUD figures across counties alone (*see* Gruber Rep., Dkt. # 2000-6 ¶ 81), and addressed this limitation by focusing on the relationship over time between shipments to counties and the

particular harm of opioid mortality. *Id.* ¶ 82 (“To remedy this potential limitation of cross-sectional analysis, I evaluate changes over time in opioid mortality across different geographic areas.”). This cherry-picking of data points by Defendants thus does nothing to undermine Prof. Gruber’s analysis.

Nor do Defendants’ generalized attacks on Prof. Gruber for failing to differentiate between correlation and causation, *see, e.g.*, Defs.’ Brief at 5-6, provide any basis for the Court to exclude his testimony. *See generally Etherton v. Owners Ins. Co.*, 829 F.3d 1209, 1220 (10th Cir. 2016) (“Although correlation alone may be insufficient to establish causation, it is nonetheless relevant to identifying causal relationships.”) (citations omitted); *United States v. Valencia*, 600 F.3d 389, 425 (5th Cir. 2010) (“[W]here evidence of correlation itself is potentially relevant and unlikely to mislead the jury, an expert who reliably discerns this relationship can present such conclusions to the jury.”); *U.S. v. W.R. Grace*, 504 F.3d 745, 765 (9th Cir. 2007) (“[T]he fact that a study is associational—rather than an epidemiological study intended to show causation—does not bar it from being used to inform an expert’s opinion”); *see also Reference Manual* at 309 (*Multiple Regression*) (“Pointing to the possibility of a spurious correlation will typically not be enough to dispose of a statistical argument.”). Simply because Prof. Gruber did not perform a regression analysis for each and every one of his analyses is certainly no basis to exclude all his opinions.

For these reasons, Prof. Gruber’s core causation opinion that increased shipments led to increased harms is based upon reliable economic methodologies and should not be excluded.

C. Professor Gruber’s Aggregate Statistical Analysis, by Definition, Does Not Isolate Any Particular County, Much Less the Bellwether Counties.

Prof. Gruber’s primary assignment was to provide an economic overview of the nation’s opioid crisis, and to determine whether, to a reasonable degree of certainty in the field of economics, shipments of prescription opioids—including those unequivocally caused by Defendants—contributed to the growth in the misuse of opioids and the increases in licit and illicit opioid-related

harms over the past twenty years. Gruber Rep., Dkt. # 2000-6 ¶ 15.⁷ These analyses examined a broad set of geographic areas as cross-area comparisons to provide more certainty about the relationships between shipments and harm. Thus, these analyses assist the trier of fact with an important economic overview and initial framework regarding the impact of shipments on harms, including the illicit opioid-related harms that many areas of the country and in particular the Bellwether Counties have experienced in recent years. And as set forth above, these analyses incorporate a large set of data from over 400 large counties—including Cuyahoga and Summit Counties—to examine the statistical trends and patterns between prescription opioid shipments and opioid-related harms.

Defendants suggest, however, that Prof. Gruber's opinions should be excluded because he failed to specifically focus on shipments and harms in the Bellwether Counties.⁸ This argument fundamentally misconstrues how empirical analysis is performed, as well as the specific purpose of this portion of Prof. Gruber's analysis. The very point of the analysis was to assess whether there was a consistent relationship between shipments and harms in a large number of different places. If the relationship between the two remained consistent across a variety of localities with different characteristics, then the inference that the number of shipments affected the harms would be valid. As is appropriate for a statistical study, Prof. Gruber utilized a number of different variables from various datasets over a long period of time to clearly and causally show a relationship between shipments and harms based on these different inputs. Part of the analysis requires specific focus on places with the highest and the lowest shipments, *in order to better assess the correlation as a whole*. Because neither Cuyahoga County nor Summit County was in the high or low quartile of shipments received in the 400-plus counties examined by Prof. Gruber, it would have been methodologically *improper* to

⁷ As explained elsewhere, other Plaintiffs' experts look specifically at harms within the Bellwether Counties. *See, e.g.*, Expert Reports of Dr. Craig McCann and Lacey Keller. It was not necessary for Prof. Gruber to perform this analysis as well.

⁸ This argument is more appropriately related to Defendants' separate argument that Prof. Gruber's opinions are irrelevant and do not fit Plaintiffs' claims, but Plaintiffs nevertheless analyze and respond to this argument here as Defendants framed it as a challenge to reliability.

include these counties in the portions of the analyses designed specifically to examine those quartiles.

Indeed, Prof. Gruber described the purpose of this analysis during his deposition:

Whenever we do analysis type in economics, be it through regression analysis or through this kind of graphical representation of the data, we're looking for central tendencies in the data. We don't claim that every single observation lines up with what's shown in those central tendencies, *but that's not the purpose*. The purpose is to draw ultimately causal conclusion, *and the causal conclusion will be based on the central tendency in the data, not the behavior of any single observation*.

Gruber Dep., Dkt. # 1962-15 at 408:7-23 (emphasis added). The thrust of Prof. Gruber's empirical analysis is to examine trends based on the 400-county sample set he analyzed, not to focus on one or two counties. Data about how shipments were correlated with harms across large swaths of the country provide important information about the causal relationship between shipments and harms.

Moreover, Defendants are simply incorrect in claiming that Prof. Gruber failed to address or analyze the Bellwether Counties altogether. He devotes an entire section of his report to discussing the opioid crisis in these counties, including identifying the amount of prescription opioid shipments Cuyahoga and Summit Counties received relative to the rest of the country, the counties' opioid mortality rates relative to the rest of the country, and general fentanyl trends in Ohio. Gruber Rep., Dkt. # 2000-6 ¶¶ 64-71. He also concludes that economic and demographic factors *cannot* explain the rise in opioid mortality in recent years, showing that the observed increases greatly exceed increases in non-opioid drug overdose mortality rates in the Bellwether Counties. *Id.* ¶¶ 106-107.

As a result, Defendants' argument that Prof. Gruber's opinions are unreliable because he failed to address the Bellwether Counties is incorrect and misconstrues the empirical rationale for his analysis, and therefore provides no basis under *Daubert* to exclude his opinions.

D. Professor Gruber's Use of Epidemiological and Economic Studies Further Underscores the Reliability of His Opinions.

Prof. Gruber also relied on epidemiology studies and economic literature to support his opinion that increased prescription shipments caused increased harms from *illicit* opioid use. Prof. Gruber observes that "mortality involving heroin accelerated sharply following the end of the dramatic

20-year increase in shipments of prescription opioids.” Gruber Rep., Dkt. # 2000-6 ¶ 88. Based on both epidemiology studies, *id.* ¶¶ 89-94, and economic literature, *id.* ¶¶ 95-98, he concludes that “the illicit opioid crisis that started in 2010 is the direct consequence of the defendants’ shipments of prescription opioids in prior years.” *Id.* ¶ 99.

Although Plaintiffs address the “gateway” theory of causation between prescription opioid use and illicit heroin and fentanyl use more exhaustively elsewhere, *see* Pls.’ Opp. to Defs.’ Mot. to Exclude “Gateway” Opinions of Drs. Lembke, Gruber and Keyes, Prof. Gruber appropriately relied on the above materials in formulating this part of his causation opinion. Under Rule 703:

An expert may base an opinion on facts or data in the case that the expert has been made aware of or personally observed. If experts in the particular field would reasonably rely on those kinds of facts or data in forming an opinion on the subject, they need not be admissible for the opinion to be admitted.

Fed. R. Evid. 703. There is no question that Prof. Gruber, a specialist in the economics of health and public finance, *see* Gruber Rep., Dkt. # 2000-6 ¶ 2, may rely on literature in his own field of economics in formulating his expert opinions. *See generally Ramirez v. Debs-Elias*, 407 F.3d 444, 449 (1st Cir. 2005) (“[S]cholarly literature is information reasonably relied upon by medical experts.”); *Mannino v. Int’l Mfg. Co.*, 650 F.2d 846, 853 (6th Cir. 1981) (bio-mechanical engineering expert may rely upon “studies . . . and upon literature and information furnished him by plaintiff’s attorney” in forming opinions). Furthermore, the Evans and Alpert economic studies he relies on and analyzes are consistent with the results of his own analysis showing that illicit opioid-related harms were a direct and causal result of initial prescription opioid shipments.

He also may rely upon epidemiology studies of the relationship between prescription and illicit opioid use. “Epidemiology is the field of public health and medicine that studies the incidence, distribution, and etiology of disease in human populations.” *Reference Manual* at 551 (Michael D. Green, et al., *Reference Guide on Epidemiology*); *see also Smtih v. Pfizer, Inc.*, 714 F. Supp. 2d 845, 849 (M.D. Tenn. 2010) (“[E]pidemiology . . . is a field that deals with questions of general causation by examining

evidence of risk of disease within groups of individuals.”). Courts generally regard epidemiology studies as highly reliable evidence of general causation of a health condition. *See, e.g., DeLuca v. Merrell Dow Pharms., Inc.*, 911 F.2d 941, 954 (3d Cir. 1990) (“The reliability of expert testimony founded on reasoning from epidemiological data is generally a fit subject for judicial notice”); *In re Meridia Prods. Liab. Litig.*, 328 F. Supp. 2d 791, 800 (N.D. Ohio 2004) (“Epidemiologic studies are the primary generally accepted methodology for demonstrating a causal relation between the chemical compound and a set of symptoms or a disease.”) (quoting *Conde v. Velsicol Chem. Corp.*, 804 F. Supp. 972, 1025-26 (S.D. Ohio 1992)).

Although not a medical doctor, Prof. Gruber may testify as a public health economist about how economists would consider the outcomes of epidemiology studies if the proper foundation for the studies is laid through qualified medical experts. *See United States ex rel. King v. Solvay S.A.*, No. H-06-2662, 2016 WL 1107014, at *3 (S.D. Tex. March 22, 2016) (economics expert Richard A. Mortimer may not “testify about conclusions he personally drew from medical studies. However, if [defendant] lays the proper foundation with clinical experts at trial, Mortimer may testify about how economists generally would consider these outcomes in their calculations.”). The cited studies and literature thus underscore the reliability of Prof. Gruber’s opinion as to illicit opioid use.

In opposing admissibility of this opinion, Defendants rely primarily on the purportedly contrary opinion set forth in the Cicero article. *See* Defs’. Brief at 11 (citing Cicero et al., *Increased use of heroin as an initiating opioid of abuse: Further considerations and policy implications*, 87 Addicted Behaviors 267-69 (2018)). The Court need not, and indeed may not, engage this debate, however, because the existence of competing opinions is not grounds for exclusion of expert testimony. *See, e.g., Schultz v. Akzo Nobel Paints, LLC*, 721 F.3d 426, 433 (7th Cir. 2013) (“Rule 702 did not require, or even permit, the district court to choose between those two studies at the gatekeeping stage. Both experts were entitled to present their views, and the merits and demerits of each study can be explored at trial.”);

Ambrosini v. Labarraque, 101 F.3d 129, 141 (D.C. Cir. 1996) (“By attempting to evaluate the credibility of opposing experts and the persuasiveness of competing scientific studies, the district court conflated the questions of the admissibility of expert testimony and the weight appropriately to be accorded such testimony by a fact finder.”); *In re Gadolinium-Based Contrast Agents Prods. Liab. Litig.*, No. 1:08 GD 50000, 2010 WL 1796334, at *3 (“*Daubert* neither requires nor empowers trial courts to determine which of several competing scientific theories has the best provenance.”) (quoting *Ruiz-Troche v. Pepsi-Cola*, 161 F.3d 77, 85 (1st Cir. 1998)).⁹

In sum, Prof. Gruber’s opinion that increased prescription opioid shipments caused illicit opioid-related harms is based upon reliable methodologies and should not be excluded.

III. PROFESSOR GRUBER’S OPINIONS ARE PLAINLY RELEVANT AND THEREFORE FIT PLAINTIFFS’ CLAIMS.

Defendants next contend that Prof. Gruber’s opinions are somehow irrelevant to Plaintiffs’ claims that, among other things, Defendants caused an unreasonable interference with the public health and safety in the Bellwether Counties, and that Defendants are liable for the increased costs Plaintiffs incurred and will continue to incur as a result of Defendants’ unlawful marketing and distribution of prescription opioids. This argument once again ignores the basic and straightforward conclusions reached by Prof. Gruber that will assist the trier of fact in understanding that greater shipments led to greater harms.

A. Professor Gruber’s Use of Aggregate Evidence Establishes Fit.

Prof. Gruber’s causation opinions are relevant to and fit Plaintiffs’ claims that Defendants’ unlawful conduct caused harms in their respective counties because the opinions provide a statistical

⁹ In any event, the Cicero study cited by Defendants as well as the underlying study it seeks to expand upon does not contradict Prof. Gruber’s fundamental opinion that the increase in the supply of heroin resulting from prescription-related demand led to more new heroin users that did not start on prescription opioids. *See* Cicero, 87 Addicted Behaviors at 267 (acknowledging that “the more commonly studied progression [is] from prescription opioids to heroin”); *see also* Cicero et al., *Increased use of heroin as an initiating opioid of abuse*, 74 Addicted Behaviors 63-66 (2017) (“[T]hose already dependent on prescription opioids were faced with a dilemma: find more money to buy harder to find and more expensive prescription opioids, or find a cheaper alternative. For many, the solution was a transition to heroin, a popular alternative given its steadily lower price, making it more widely accessible and with a high comparable, if not stronger, than prescription opioids.”) (emphasis added).

analysis based on a broad set of data, including through the basic economic and regression analyses mentioned above. As noted above, the graphical analyses are basic and straightforward economic tools to establish relationships between variables, and opinions based on regression analysis are routinely admitted as reliable. *See In re Neurontin*, 712 F.3d at 42; *see also In re High Fructose Corn Syrup Antitrust Litig.*, 295 F.3d 651, 660-61 (7th Cir. 2002) (affirming district court’s admission of economic experts’ competing regression analyses of price effect in antitrust case); *Comwood Co.*, 290 F.3d at 793 (regression analysis used by economic expert was “generally accepted”).

In arguing to the contrary, Defendants fault Prof. Gruber for failing “to link alleged wrongdoing by any particular Defendant, or even all of them jointly, to specific harms in Summit and Cuyahoga Counties.” Defs.’ Brief at 12-13. But this argument once again misses the point of Prof. Gruber’s report. The absence of specific Defendant-level analysis does not undermine the relevance of Prof. Gruber’s opinion that greater prescription opioid shipments led to increased harms. As the Court has previously recognized, this analysis clearly is relevant to Plaintiffs’ central claims that Defendants’ misconduct caused increased costs in the Bellwether Counties. *See* Report and Recommendation of Magistrate Judge David A. Ruiz, Dkt. # 1025 at 27 (Plaintiffs “injuries plainly stem from opioid use/abuse and not some possible other source. This court cannot find, absent any discovery, that Plaintiffs’ injuries were incidental to the alleged fraud or the oversupply/diversion of opioids.”). In any event, Plaintiffs did not ask Prof. Gruber to analyze Defendant-specific misconduct. *See* Gruber Rep., Dkt. # 2000-6 ¶ 15. Instead, other experts have been tasked with analyzing the impact of individual Defendants’ misconduct. *See, e.g.*, Report of Professor Meredith Rosenthal, Dkt. # 2000-23, Report of Professor David Cutler, Dkt. # 2000-4, Report of Craig J. McCann, Ph.D., CFA, Dkt. # 2000-14, 2000-15, 2000-16, and Report of James E. Rafalski, Dkt. # 2000-22. The Court thus should reject Defendants’ argument that Prof. Gruber must provide party-specific evidence for his opinions to be relevant and admissible.

B. Ample Evidence Supports Professor Gruber's Conclusion that Harms Due to Illicit Opioids Are a Direct Result of Defendants' Excessive Shipments of Prescription Opioids.

Finally, Defendants argue that Prof. Gruber's opinions do not "fit" Plaintiffs' claims because he failed to connect Defendants' conduct to the Plaintiffs' injuries. *See* Defs.' Brief at 12. Defendants purport to identify four ways in which Prof. Gruber's analysis fails to connect with the injuries at issue in this case, but are incorrect about each of them.

Defendants' first two arguments about "fit" are simply rehashes of their arguments about reliability, and should be rejected for the same reasons. The fact that Prof. Gruber analyzed nationwide trends in a 400-county analysis does not mean that his results have *no* applicability to Summit and Cuyahoga Counties. Rather, as discussed above, his findings about the relationship between opioid shipments and harms across the United States support and explain Plaintiffs' other evidence about the causal connection specifically in Summit and Cuyahoga Counties. Defendants ask this Court to ignore that the opioid epidemic in the Bellwether Counties is part of a larger nationwide crisis; there is simply no justification for their insistence that Plaintiffs' experts analyze the injuries in Summit and Cuyahoga Counties without reference whatsoever to the similar injuries in other places in the country.

Next, Defendants repeat, under the rubric of "fit" their argument that Prof. Gruber does not offer opinions about specific Defendants. But as discussed above, it is not necessary for Prof. Gruber to do this. *See supra* § II.C.

Third, Defendants argue that Prof. Gruber fails to distinguish the impact of illicit opioids. But this is simply not true. One of Prof. Gruber's fundamental analyses examines through a variety of statistical and empirical approaches why the increase in illicit opioid-related harms—including harms caused by heroin and fentanyl abuse that the Bellwether Counties have experienced in recent years—was a direct result of initial shipments of prescriptions opioids. Gruber Rep., Dkt. # 2000-6 ¶ 16. In particular, he performs several economic analyses to support this conclusion, many of which have

been described above. He first examines prescription opioid mortality, heroin and fentanyl mortality, and total opioid mortality rates in hundreds of counties over nearly twenty years in relation to shipments to conclude that areas receiving greater shipments experienced greater illicit mortality post-2010. *Id.* ¶¶ 84-87. Prof. Gruber supplements this analysis by then providing evidence from epidemiological and economic studies that corroborate his conclusion that illicit harms since 2010 were a direct result of shipments and licit harms. *Id.* ¶¶ 88-99; *see also supra* § II.D. He then utilizes a regression analysis to conclude that economic, demographic, and social conditions do not explain the emergence of illicit harms since 2010. Gruber Rep., Dkt. # 2000-6 ¶¶ 100-107. Prof. Gruber also reviews and analyzes data on trends and regional patterns of shipments of prescription opioids and illicit opioid mortality, data on confiscations of illegal drugs, and evidence and conclusions from state and federal regulators regarding the transition from prescription to illicit opioid abuse after 2010. *Id.* ¶¶ 46-63. Thus, Defendants have no basis to contend that Prof. Gruber has failed to perform any meaningful analysis in establishing the link between shipments and illicit harms.

Defendants' final contention that Prof. Gruber has failed to apportion how certain factors allegedly beyond Defendants' control—including for instance state drug monitoring programs or state caps on prescriptions—influenced illicit use is a red herring. Defs.' Brief at 13.¹⁰ It is irrelevant to Prof. Gruber's methodology and modeling whether and to what extent these factors drove individuals to illicit use because his fundamental analysis is to examine the relationship between shipments and illicit harms. *Daubert* simply does not permit parties to raise a never-ending list of what-ifs to bar the admissibility of expert testimony. *See, e.g., Best v. Lowe's Home Ctrs., Inc.*, 563 F.3d 171, 181 (6th Cir.

¹⁰ In any event, Prof. Gruber has explicitly considered and discussed these factors in an entire section of his report. *See* Gruber Rep., Dkt. # 2000-6 ¶¶ 41-45. In addition, he identified these factors to show that the crisis evolved from overdose deaths involving prescription opioids to rapid increases in overdoses involving heroin and fentanyl beginning in 2010, a point in time recognized by nearly every public health organization, including the CDC. *See Understanding the Epidemic*, Ctrs. for Disease Control and Prevention, <https://www.cdc.gov/drugoverdose/epidemic/index.html> (last updated Dec. 19, 2018).

2009) (“[D]octors need not rule out every conceivable cause in order for their differential-diagnosis opinions to be admissible. . . . Admissibility under Rule 702 does not require perfect methodology.”).

Defendants’ challenge to this particular aspect of Prof. Gruber’s opinion also defies common sense and logic – as previously explained by the Court in denying Defendants’ Motion to Dismiss:

When there is a flood of highly addictive drugs into a community it is foreseeable—to the point of being a foregone conclusion—that there will be a secondary, “black” market created for those drugs. It is also foreseeable that local governments will be responsible for combatting the creation of that market and mitigating its effects.

See Op. and Order on Motions to Dismiss, Dkt. # 1203 at 35. As set forth in the studies cited by Prof. Gruber and elsewhere, it is commonly understood and accepted that there is a strong and causal link between prescription opioid use and the related harms caused by abuse of illicit opioids.¹¹ Defendants ignore this reality, and their arguments to exclude Prof. Gruber’s opinions are yet another instance of their continued attempt to disclaim any liability for the massive harms caused by their manufacturing and distribution of prescription opioids.

CONCLUSION

For the foregoing reasons, this Court should deny Defendants’ *Daubert* Motion to Exclude the Opinions Offered by Jonathan Gruber.

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Respectfully submitted,

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¹¹ *See, e.g.*, National Academies of Sciences, et al., *Pain Management and the Opioid Epidemic: Balancing Societal and Individual Benefits and Risks of Prescription Opioid Use*, Ch. 4, Trends in Opioid Use, Harms, and Treatment, (National Academies Press 2017), <https://www.ncbi.nlm.nih.gov/books/NBK458661/> (“A number of studies have yielded evidence strongly supporting the conclusion that the recent prescription opioid epidemic has resulted in a significant increase in domestic heroin use and associated overdose deaths.”).

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